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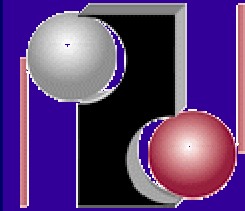
**Document Management Practices  
in a Technologically Diverse,  
Geographically Distributed Virtual  
Development Team**



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# Objectives

- Using the Protodigm Tempium project as a case study, identify significant issues for EDM implementation in a virtual team
- Communicate solutions and learning points involving people-technology interfaces



# Protodigm, Ltd.

- Created as a business **prototype** for a new **paradigm** by its parent, Hoffmann-La Roche
- “Driving strategic outsourcing to get medicines to market faster and more efficiently”
- Virtual development through innovative total outsourcing

# The Tempium Project

- Resurrected a terminated development program for CNS drug
- Initiated and completed Phase III studies
- Created virtual teams for clinical, nonclinical, CMC, and regulatory
- Goal: global regulatory submissions shortly after completion of Phase III studies

# The Tempium Virtual Development Team

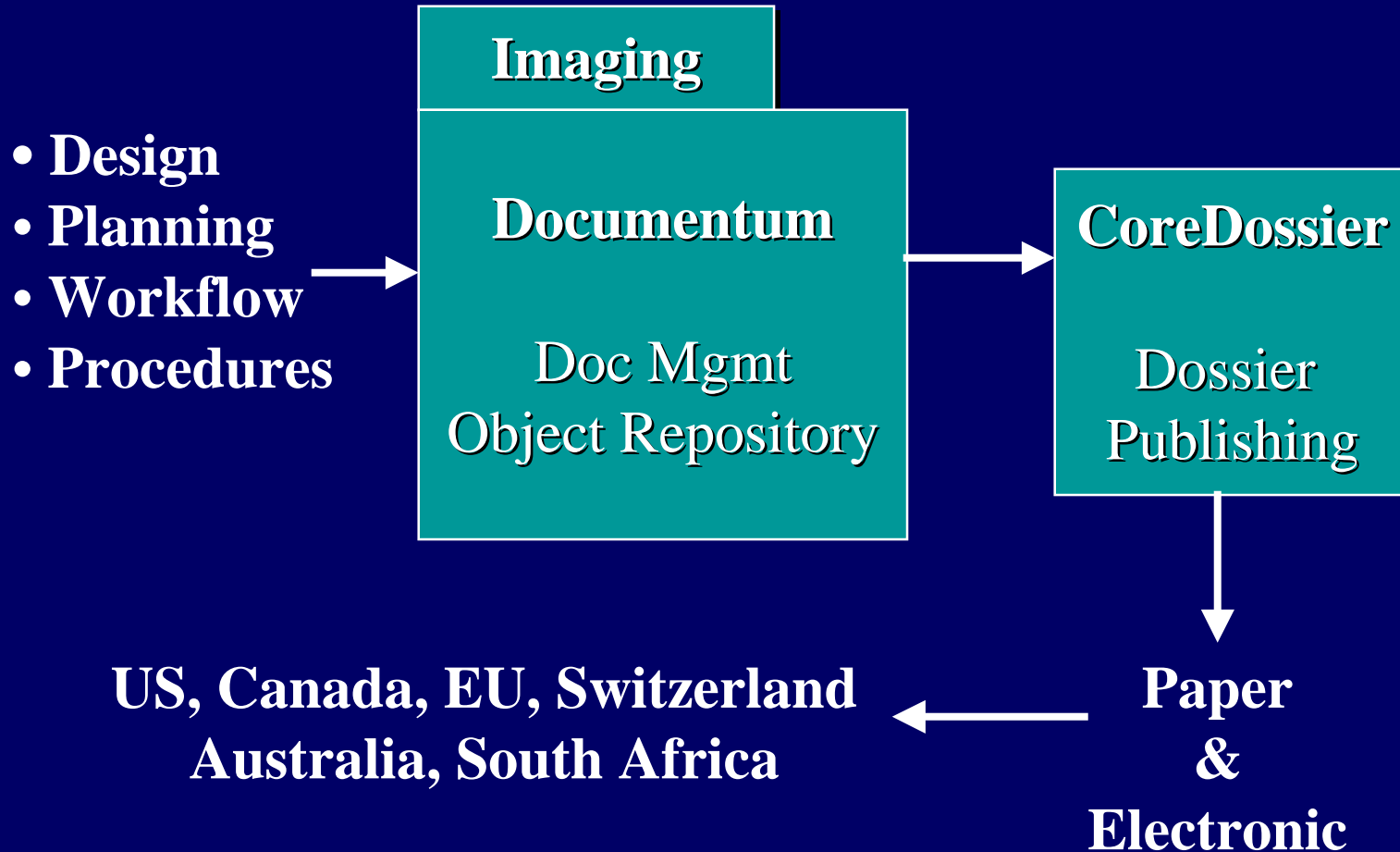


**27 users at 15 sites in 5 countries  
(US, Canada, UK, France, Switzerland)**

# The Tempium Virtual Development Team

- Geographically Distributed
- Support/Infrastructure Diversity
  - Individual consultants to multinational pharmaceutical company
- Technologically Diverse
  - Technophiles
  - Technophobes

# Components of Global Dossier System



# EDM Issues in the Tempium Project

- Define Business Objectives
- Prepare for Change
- Evaluate Users Constraints
- Decide on EDM System and Components
- Team Training
- Production and Maintenance Issues
- Document Coordination

# Define Business Objective

To efficiently and quickly produce approvable submissions to worldwide regulatory authorities using state-of-the-art electronic tools

# Prepare for Change

- Most of effort focused on non-technical issues such as:
  - culture shock - “knowledge sharing” mentality
  - cooperation across the virtual team
  - top-down commitment and setting examples

# Evaluate User Constraints

- Platform and speed/connectivity issues
- User experience/comfort level
  - comfort with technology in general
  - fear of change from old ways
- Required use or as needed basis
- User's input into repository organization
- Balance training issues with technical expertise to use time most effectively

# Major Factors in EDM System Decision-Making Process

- Experience of EDM system in industry
- Connectivity for virtual development team
- Ease of use/training
- Synchronization with publishing system
  - ultimate goal - timely, approvable submissions

# Team Training

- Different modes for different people
- Sell It; get team buy-in
- Cheerleading

“Point me to the  
URL and I’ll  
run with it”



“What’s a  
URL?”

# Training Techniques

- Webpage with instructions, hyperlinks, FAQs, etc.
- Documents defining specific processes
  - creating document, checking in, checking out
- Writer's workshops
  - Walk-thru procedures for document creation, revision, finalization
- One-on-one training with hands-on practice

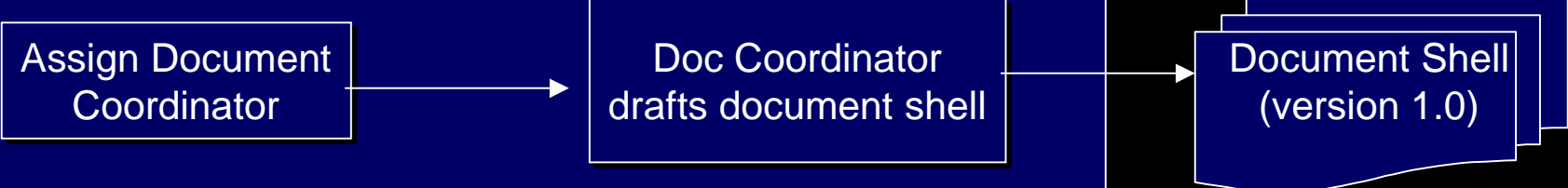
# Production and Maintenance Issues

- IT support across timezones
- Backup/restore integrity issues
- Calm fears that arises during crunch/crisis time
- Continually update team on system status
- Reassure periodically that project is on track

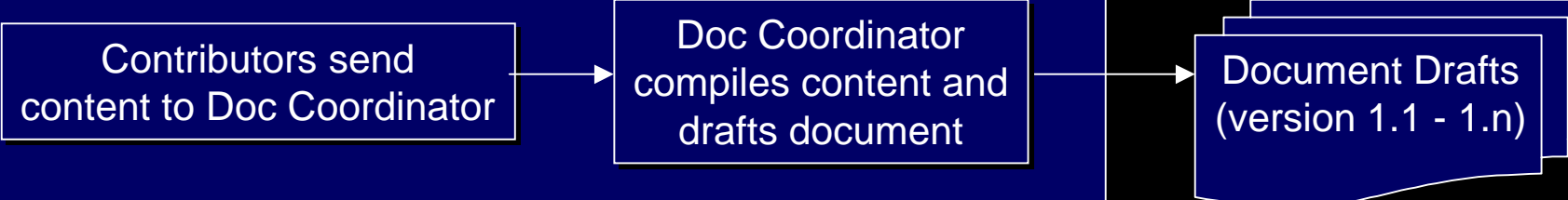
# Document Coordination

- Balances EDM use with people constraints
- Allows for **flexibility** across EDM users
  - Full, robust use of all EDM has to offer
  - Partial EDM feature use
  - Simple repository storage of final version
- Provides framework for authoring, review and finalization of documents within the EDM environment

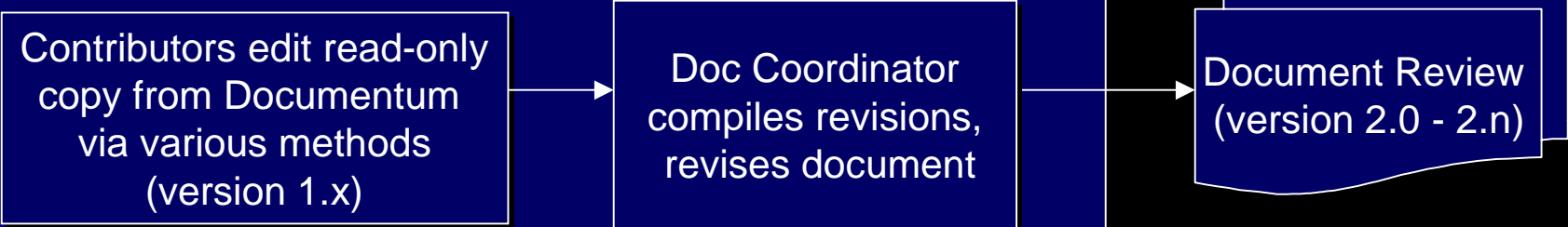
### 1. Document Initiation



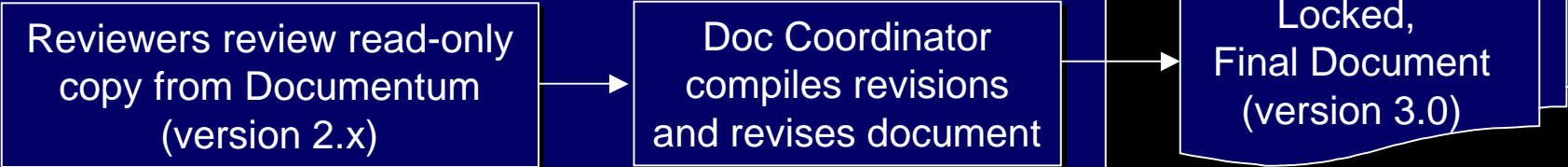
### 2. Authoring First Draft



### 3. Content Review and Revisions



### 4. High-Level Review and Finalization

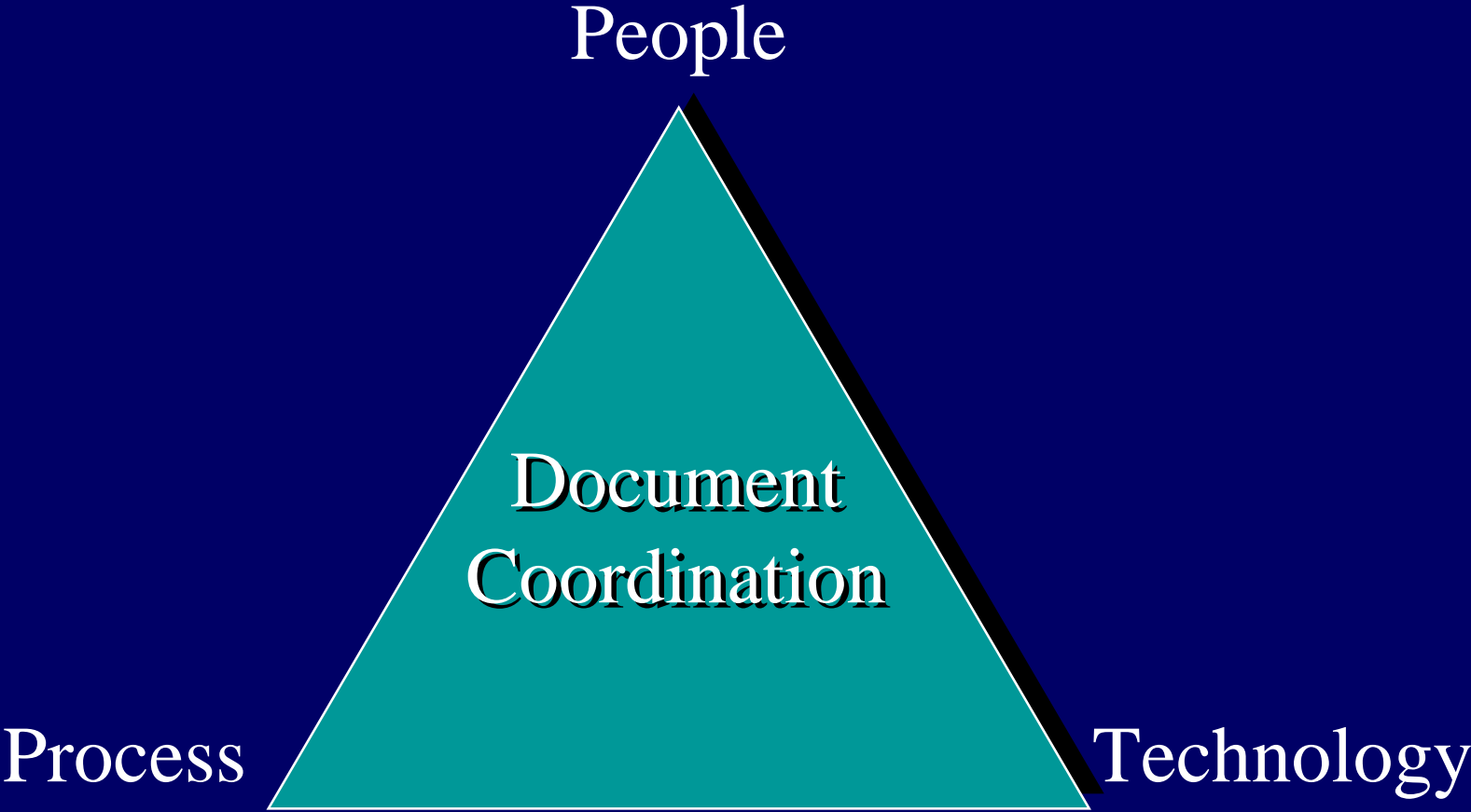


# Lessons Learned

- People still need face-to-face interactions
- Support/training needs to be tailored to the particular person's abilities, constraints, comfort and predilection

# Lessons Learned

- Incremental steps and thorough training are the keys to buy-in and adoption
- Critical to balance and optimize the relationships between people, technology and processes
  - balance paper, human, EDM and other electronic processes



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